K05 1392

JUN 29 2005

GLOBAL HARMONIZATION PILOT 510 (K) SUBMISSION
BTI-Scan

510 (K) SUMMARY

510 (K) SUMMARY. SAFETY AND EFFECTIVENESS INFORMATION
BTI-SCAN

SUBMITTER'S NAME. ADDRESS AND TELEPHONE NUMBER:	B.T.I. Biotechnology Institute, S.L. Parque Tecnológico de Álava Leonardo da Vinci, 14 B Miñano (Álava) 01510 Spain PH: 34 945 297030 FAX: 34 945 297031
CONTACT PERSON	Leyre Zúñiga Hernando Quality and Regulatory Affairs Pharmacist
SUMARY PREPARATION DATE:	May 2005
ESTABLISHMENT REGISTRATION No:	3004417597
PROPRIETARY NAME:	BTI-Scan
COMMON NAME:	Image Processing System and preoperative software for simulating/ evaluating dental implant placement and surgical treatment options
CLASSIFICATION NAME:	Image Processing System (Sec. 892.2050)
PRODUCT CODE:	LLZ
DEVICE CLASSIFICATION:	Class II

PREDICATE DEVICE
The BTI-Scan is claimed to be substantially equivalent in material, design, and function to the SimPlant System cleared by FDA under 510 (k) K033849 on May 25, 2004

DEVICE DESCRIPTION
BTI Scan is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical CT scanner. It is also intended as a pre-operative software for simulating / evaluating dental implant placement and surgical treatment options.

INTENDED USE

BTI Scan is intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical CT scanner. It is also intended as a pre-operative software for simulating / evaluating dental implant placement and surgical treatment options.

SUBSTANTIAL EQUIVALENCE

The BTI-Scan is considered to be substantially equivalent to the SimPlant System

CONCLUSION

The BTI-Scan is considered to be substantially equivalent in design, material and function to the SimPlant System

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 2005

Mr. Leyre Zúñiga Hernando
Quality and Regulatory Affairs Pharmacist
B.T.I. Biotechnology Institute, S.L.
Leonardo da Vinci, 14-B
Miñano Menor, Álava, 01510
SPAIN

Re: K051392
Trade/Device Name: BTI-Scan
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 18, 2005
Received: June 1, 2005

Dear Mr. Hernando:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051392

Device Name: BTI-Scan

Indications for Use:

BTI-Scan is indicated for use as a medical front-end software that can be used by medically trained people for the purpose of visualizing gray value images. It is indicated as a software interface and image segmentation system for the transfer of imaging information from a medical CT scanner. It is also indicated for use as a planning and simulation software for dental implant placement and surgical treatment.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) ~~AND~~/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K051392